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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stephen Griffin

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/025,668	Applicant(s) GRIFFIN ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008 and 04 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-16,20,24-38 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-16,20,24-38 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/4/08 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5 – 16 and 37 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 1 states "an elongate core wire comprising a portion formed of a super elastic nickel titanium alloy which is **not independently shapeable**". However, the specification fails to describe how to make a core formed of a super elastic nickel titanium alloy that is not capable of being shaped. Although, super elastic nickel titanium alloys may have a high kink resistance, provided enough force permanent deformation can take place after reaching the elastic limit.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

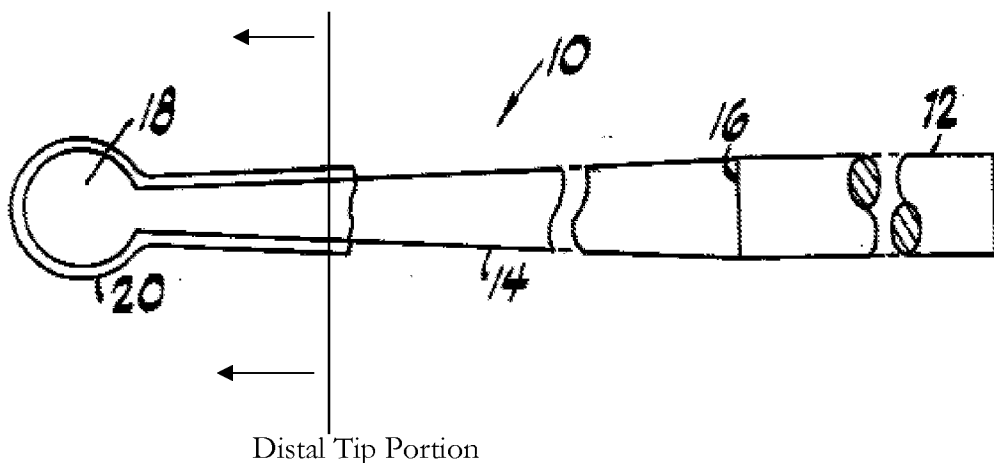
5. Claims 1, 5, 6, 20, 24, 25, 36 - 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepfel.

6. In regard to claims 1, 5, 6 and 37, Raman et al. disclose an elongate core wire comprising a portion formed of a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col. 5, lines 15 – 16) which is not independently shapeable (Col. 3, lines 1 – 8). Raman et al. disclose a formable cladding (20) attached to and surrounding the portion of the core wire formed of a super elastic nickel titanium alloy, the cladding is in continuous contact with the core wire throughout a majority of the length of the cladding, the cladding is more stiff than the portion of the guidewire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). The portion of the core wire surrounded by the cladding includes a tapered portion and is bent into a curved shape and maintains the curved shape (Col. 4, lines 66 – 68) by overcoming biasing forces imposed by the elongate core wire which tend to straighten the core wire. However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of

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polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained (Col. 4, lines 51 – 65). Schroepel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

7. In regard to claims 20, 24, 25 and 38, Raman et al. disclose an elongate core wire comprising a distal tip portion (See Below) formed of a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col. 5, lines 15 – 16) having an elastic limit.



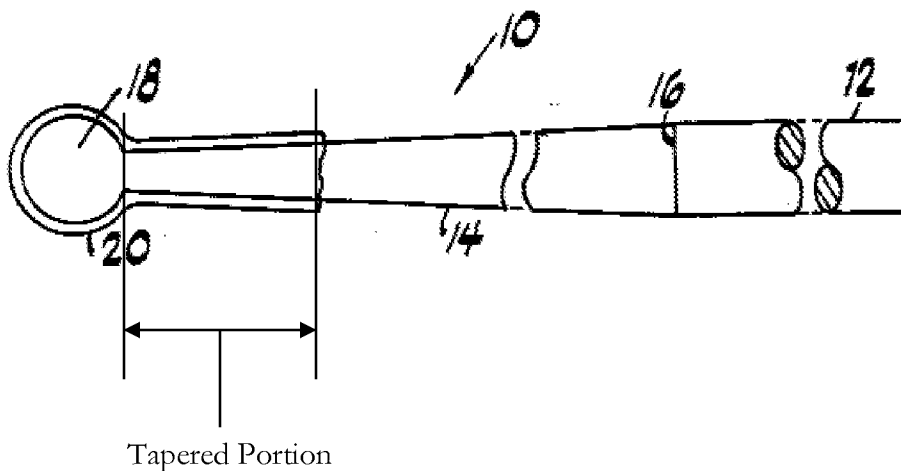
Raman et al. disclose a formable cladding (20) surrounding the entire distal tip portion such that a substantial portion of the cladding is in continuous contact with the core wire, the cladding is more stiff than the distal tip portion of the guidewire which it surrounds to allow a physician to

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impart a shape to the distal tip (Col. 5, lines 6 – 14). The portion of the core wire surrounded by the cladding is bent into a curved shape and maintains the curved shape (Col. 4, lines 66 – 68) by overcoming biasing forces imposed by the elongate core wire which tend to straighten the core wire. However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained (Col. 4, lines 51 – 65). Schroepfel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepfel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

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8. In regard to claim 36, Raman et al. disclose an elongate core wire comprising a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col. 5, lines 15 – 16) having a tapered portion (See Below) and a distal end (18).



Raman et al. disclose a formable cladding (20) attached to a surrounding a portion of the core wire including the entire tapered portion and the distal end (18) of the core wire such that the cladding (20) is in continuous contact with the core wire throughout a majority of the length of the cladding. The cladding (20) is more stiff than the portion of the core wire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it

Raman et al. disclose a formable cladding (20) attached to and surrounding at least the distal portion of the core wire formed of a super elastic nickel titanium alloy, the cladding is in continuous

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contact with the core wire throughout a majority of the length of the cladding, the cladding is more stiff than the portion of the guidewire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). The portion of the core wire surrounded by the cladding includes a tapered portion and is bent into a curved shape and maintains the curved shape (Col. 4, lines 66 – 68) by overcoming biasing forces imposed by the elongate core wire which tend to straighten the core wire. However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepfel discloses a guiding element for positioning within a patient's body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained (Col. 4, lines 51 – 65). Schroepfel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepfel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

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10. Claims 7 – 16 and 26 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepfel as applied to claims 1 and 20 above, and further in view of U.S. Patent No. 6,485,458 to Takahashi.

In reference to claims 7 – 16 and 26 - 35, Raman et al. in view of Schroepfel disclose a shape memory polymer surrounding a portion of the core wire being polynorborene, polyurethane and similar materials (Col. 7, lines 46 – 50), but fails to disclose the polymer being polycaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Raman et al. in view of Schroepfel in that Takahashi teaches that shape memory polymers are interchangeable.

Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Raman et al. in view of Schroepfel with any other shape memory polymer is a design consideration within the skill of the art.

Response to Arguments

11. Applicant's arguments filed 9/4/08 have been fully considered but they are not persuasive. In regard to the rejections under 35 U.S.C. 112 first paragraph, Applicant asserts that it is well known in the art that super-elastic nickel titanium alloy cannot be shaped to a desired form under

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the forces normally encountered during use as part of a medical device. However, claim 1 does not include limitations related to forces normally encountered during use as a part of a medical device. Claim 1 states that the elongate core wire comprises a “super elastic nickel titanium alloy which is not independently shapeable”. However, as previously set forth, super elastic nickel titanium alloy may have a high kink resistance, but it can still be permanently deformed. Applicant has failed to enable one skilled in the art to make a core wire of super elastic nickel titanium alloy that has no elastic limit (i.e. that is not independently shapeable). Claims 1, 20, 36 and 45, each recite some variation of a “portion” of the core wire. It is noted that the transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,’ the terms containing’ and mixture’ are open-ended.”).< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) (“The transition comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to “a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades” encompasses razors with more than three blades because

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the transitional phrase. “comprising” in the preamble and the phrase “group of” are presumptively open-ended. “The word comprising’ transitioning from the preamble to the body signals that the entire claim is presumptively open-ended.” Id. In contrast, the court noted the phrase “group consisting of” is a closed term, which is often used in claim drafting to signal a “Markush group” that is by its nature closed. Id. The court also emphasized that reference to “first,” “second,” and “third” blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. Id. < MPEP 2111.02. In the present case, the core wire disclosed by Raman et al. comprises a plurality of “portions”. Applicant asserts that since Raman et al. disclose the cladding terminating at a location that leaves at least a section of superelastic alloy exposed, that Raman et al. teach away from the claimed invention.

However, claim 1 recites, in part, "an elongate core wire comprising **a portion** formed of a super elastic nickel titanium alloy...and a polymer jacket comprising a shape member polymer attached to and surrounding **the portion** of the core wire formed of a super elastic nickel titanium alloy". The claim only requires **a portion** of a super elastic nickel titanium alloy to include a polymer jacket.

Claim 20 recites in part “an elongate core wire comprising **a distal tip portion** formed of a super elastic nickel titanium alloy...and a polymer jacket attached to and surrounding the entire distal tip portion of the core wire”. As set forth above, the Examiner considers the most distal 2 inches of the core disclosed by Raman et al. to be the claimed “distal tip portion”. As such, Raman et al. disclose the claimed features. Claim 36 recites in part “a super elastic nickel titanium alloy core wire having a **tapered portion** and a distal end; and a polymer jacket...attached to and surrounding a portion of the core wire including the entire tapered portion and the distal end of the core wire”. As set forth above, the Examiner considers the portion of the core proximal of the distal end to 2 inches from the distal end to be the claimed “tapered portion”. As such, Raman et al. disclose the

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claimed features. In regard to claim 45, Raman et al. discloses surrounding at least the distal portion of the core wire formed of a super elastic metal with a cladding thereto.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan ML Foreman/
Examiner, Art Unit 3736